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(54) IMPREGNATED STENT

IMPREGNIERTER STENT

EXTENSEUR A IMPREGNATION

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Description

This invention generally relates to a class of endoprostheses known as "stents" and more specifically to the structure and manufacture of such stents and the assembly of such stents into delivery systems.

Certain medical devices, called "stents", are well known and have a variety of forms. For example, United States Letters Patent No. 4,690,684 of September 1, 1987 to McGreevy et al for a "Meltable Stent for Anastomosis" discloses a solid stent formed of a biologically compatible material, such as frozen blood plasma or the like. According to the disclosure, a solid stent of this type may be inserted into opposed ends of a ruptured vessel to support the separated vessel walls while the ends are bonded together. The heat from the bonding operation and the body eventually melt the stent and clear the vessel.

A stent that constitutes an endoprosthesis usually comprises a tubular structure that expands radially to be implanted into the tissue surrounding a "vessel" thereby to maintain its patency. It is well known that stents may be utilized in body canals, blood vessels, ducts and other body passageways, and the term "vessel" is meant to include all such passageways. Generally speaking, a stent delivery system includes the stent and some means for positioning and fixing the stent in place. Typically, the stent delivery system includes a catheter that supports the stent in a compacted form for transport to a site of implantation. Means integral with or ancillary to the catheter then expand the stent radially into the vessel walls to be implanted at the selected site. After the catheter is removed, the stent retains an expanded shape to keep the vessel walls from closing.

Stent delivery systems must conform to several important criteria. First, it is important to keep the cross-sectional dimension of the delivery system to a minimum, so the stent must be capable of compaction against a delivery device, such as a catheter. Second, the delivery system must facilitate the deployment of the stent into contact with the vessel walls once it is located in a body. Third, the stent delivery system must easily disengage from the stent after the stent is deployed. Fourth, the procedure for removing the delivery system from the body must be straightforward. Fifth, the delivery system must operate reliably.

United States Letters Patent No. 4,922,905 of Ernst P. Strecker for a "Dilatation Catheter" describes the manufacture, construction and use of such stents. In the specific disclosure of the Strecker patent, the stent comprises a tubular structure that is knitted from metal or plastic filaments in loosely interlocked loops. A stent delivery system includes a balloon catheter and a coaxial sheath. The balloon catheter supports the compacted stent during its transport to a site within the body. The sheath covers the stent to prevent premature stent expansion and to facilitate the transfer of the stent through various passages in the body. A physician properly locates the stent, and then moves the sheath axially with respect to the catheter thereby to expose the stent. Then the physician operates a balloon pumping system to expand the balloon catheter and move the stent into a final configuration in contact with tissue surrounding the stent. When the stent expands radially, the filament material undergoes a plastic deformation. Consequently, the stent retains its new expanded shape. When the balloon subsequently deflates, it is free of the expanded stent, so the catheter, sheath and remainder of the delivery system can be withdrawn from the patient.

Commercial embodiments of the structures shown in the Strecker patent include rings for overlapping the end portions of the compacted stent thereby to eliminate the sheath. In such embodiments, however, the entire assembly of the catheter and compacted stent slides into position after passing through a previously positioned introducer sheath.

United States Letters Patent No. 4,733,655 of March 29, 1988 to Palmaz for an "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Interluminal Graft" discloses a catheter with rings for positioning a compacted stent on a balloon portion of the catheter. A sleeve encases the compact stent. When the stent is properly positioned, a physician retracts the sleeve and pumps the catheter to expand the stent into position. During its expansion the stent detaches from the mounting rings. Then the physician deflates the balloon and removes the catheter, leaving the stent in place.

EP-A-0 218 203 discloses an encapsulated expandable closing device, such a continence device in the form of a block of resilient foam material capable of being collapsed into a small volume condition and encapsulated with gelatin that surrounds the compressed foam material. The gelatin maintains the small volume condition during placement in a desired body orifice. The gelatine capsule then dissolves in the presence of body warmth and moisture to enable the compressed soft foam material to expand to a predetermined size and shape for blockage and for temporary retention of gastrointestinal contents in the body orifice.

United States Letters Patent No. 5,026,377 of June 25, 1991 to Burton et al for a "Stent Placement Instrument and Method" discloses a delivery system for a self-expanding stent. The stent is a braided structure formed of a shape memory material. An outer sleeve retains the stent radially during transport to a final site within the body. A grip member enables both deployment and retraction of the stent. There are several examples of grip members in this patent. One, for example, comprises a releasable adhesive an a support for the stent. The adhesive grips the stent without slipping while the stent is in the instrument, but allows the stent to expand when a outer sleeve is retracted.

As is known, the overall diameter and flexibility of a

stent and its delivery system determine the range of vessels that can receive a stent. it is important that any stent structure should have as small an overall diameter as possible. The smaller the diameter, the greater the range of vessels for which the endoprosthesis becomes viable. That range of vessels is limited with prior art structures, particularly by a protective sheath or the like that surrounds a stent and has two functions. First, the protective sheath provides a smooth surface over the stent to facilitate its transport through the body with minimal trauma. Second, the protective sheath prevents the stent from expanding prematurely. The second function determines the wall thickness of a sheath or like structure and with it the overall diameter of the stent delivery system. The wall must be sufficiently thick to provide the strength necessary to restrain the stent. This thickness is greater than the wall thickness required by the first function. For a given diameter stent, the overall diameter of the stent and the sheath or the like can exceed a minimal diameter. It is this characteristic that prevents the introduction of prior art stents into smaller vessels.

Therefore it is an object of this invention to provide an improved stent system.

Another object of this invention is to provide an improved stent structure that is capable of minimising the overall diameter of the stent and the apparatus for delivering the stent to a vessel.

Yet another object of this invention is to provide an improved stent structure that enables the placement of the stent in vessels that are smaller than those that could receive prior art stents.

The present invention is directed to a tubular endoprosthesis of the general type disclosed in US-A-4,922,905 and as defined in the precharacterising clause of claim 1.

According to the present invention, there is provided a tubular endoprosthesis as defined in the characterising clause of claim 1.

The prosthesis embodying this invention consist of a stent assembly that comprises a compact mesh in a cylindrical form. The mesh can expand into a cylindrical mesh stent that engages the tissue walls surrounding a vessel. A cured dissolvable material impregnates the mesh and contains the mesh in its compact form during placement. The cured material dissolves when the stent is in position in the body thereby to free the mesh and enable its expansion into a final form contacting the tissue surrounding the vessel.

Reference will now be made to the accompanying drawings, in which like reference numerals refer to like parts, and in which:

FIG. 1 depicts a stent that is adapted for use in connection with this invention;

FIG. 2 depicts a stent assembly embodying this invention;

FIG. 3 including FIGS. 3A through 3F and FIG. 4, taken together, depict manufacturing steps that convert the stent of FIG. 1 to a stent assembly as shown in FIG. 2;

FIG. 5 is a cross-sectional view of one embodiment of a stent delivery system embodying this invention;

FIG. 6 is a view of a vessel with a stent and a stent delivery system of FIG. 5 positioned therein; and

FIG. 7 is another embodiment of a stent delivery system.

FIG. 1 discloses one embodiment of tubular endoprosthesis, or a stent 10, in expanded form and constructed in accordance with the disclosure of the previously identified United States Letters Patent No. 4,922,905. In this particular embodiment the stent 10 comprises a single filament 11 that is knitted into a mesh cylinder 12 extending coaxially with an axis 13 and comprising a fabric of loosely interlocked filament loops that form the wall of the cylinder 12. The filament can be selected from two groups of materials depending upon the ultimate characteristics of the stent 10.

Generally, the filament 11 should be formed of a biocompatible material. When expanded to a final form as shown in FIG. 1, the structure should be resistant to subsequent deformation. Thus these materials normally are taken from a group of shape memory metals that maintain the stent in an expanded form. The material preferably is radiopaque.

When a stent 10 is to be self-expanding, a self-expanding material such as a super elastic material is selected so that compaction produces internal restoring forces within the material. Nitinol is an example of such a super elastic material that is particularly adapted for self-expanding stents. Obviously if the stent 10 is self-expanding, it will be necessary to contain such self-expanding stents in compact form. The stent 10 will return to the shape shown in FIG.1 when it is freed from any containment.

If some external apparatus, such as a balloon catheter, is to expand the stent 10, the stent 10 may be comprised of a material from a group of plastic deformable materials that include stainless steel and tantalum.

In accordance with another aspect of this invention, the stent 10 in FIG. 1 is compacted into a stent assembly 20 as shown in FIG. 2. As described in more detail later, compaction can produce a reduction in the overall radius of the stent 10 by a 10:1 with about a 30% increase in the overall length of the stent 10. The stent assembly 20 also includes a cured, dissolvable material that readily shifts between liquid and solid phases at a melting temperature in the range of 30°C to 40°C. This material impregnates the interstices of the mesh stent 10 and has sufficient strength to contain the stent 10 in its compact form.

There are several materials that have these characteristics, including polymers, such as resorbable polyesters or polyvinyl alcohol based materials and gelatin. Gelatin is particularly adapted for use in accordance with this invention as it transforms from a liquid form on

cooling into a cured, solid mass. The mass has sufficient strength to contain the stent 10 in its compact form, even when the stent 10 is formed of a self-expanding material. Gelatin also has the property of liquefying when heated above some predetermined temperature that is normally less than 37°C. In addition certain enzymes, such as those found in the body, will attack the gelatin and cause it to lose its strength and viscosity.

Thus, when a stent assembly 20 having a compact stent 10 and gelatin 21 as shown in FIG. 2 is introduced into the body, the body temperature and liquids that the stent assembly 20 contacts coact to liquify the gelatin. The body fluids transport the gelatin out of the system and this liquefaction releases the stent for expansion.

The rate of thermal decomposition of gelatin depends upon the type and quality of the gelatin, the temperature of the gelatin and the nature of any enzymes that may attack the solution. All these parameters can be controlled by the selection of gelatins with particular properties. Particularly, it has been found that Vee Gee Extra Fine 100 Bloom Type A gelatin or Vee Gee 100 Bloom Type B gelatin from the Vyse Gelatin Company produce satisfactory gelatins for impregnating a mesh stent.

Although the stent assembly 20 may be constructed with pure gelatin or like dissolvable materials that only contain the stent, other constituents can be added for producing other functions. For example, it is possible to mix barium or other marker materials into gelatin for assisting during fluoroscopy or other imaging techniques. Alternatively the gelatin or other material could entrain any of a number of encapsulated medicines for a timed release into the body as the material dissolves, particularly if a gelatin is designed to dissolve over a longer time period. It is also possible to combine the markers or medicines in a stent assembly comprising an axial distribution of gelatins or other materials with different rates of thermal decomposition. In such an application, the materials would release at differing times and rates. Moreover, the axial distribution could be used to control the physical profile of a the stent as it expands.

When a stent is impregnated with a cured gelatin or other material, it becomes rigid. This rigidity impairs the ability of the stent assembly 20 to pass through a tortious path to a vessel. In accordance with another aspect of this invention, a helical groove 22 in the outer cylindrical surface 23 of the stent assembly 20 facilitates bending of the stent assembly 20. As another alternative, the gelatin 21 could be located at discrete, separated axial positions along the length of the compact stent and achieve the same general results while also improving flexibility. As still another alternative a groove could be formed on an inner cylindrical surface 24 of the stent assembly 20.

The exact method of manufacture of a given stent assembly in accordance with this invention depends upon several factors. Two major factors are the final application for the stent and whether the stent 10 is formed of a self-expanding material or an expansible material that requires some external force to expand it. The manufacturing process begins with a selection of a stent 10 shown in FIG. 3A and represented by steps 41 and 42 in FIG. 4. That is, in accordance with step 41 the stent 10 in FIG. 3A would be formed of an expansible plastic deformable material, such as stainless steel or tantalum. In step 42 the stent would be selected from any of the self-expanding super elastic alloys for stent material such as Nitinol.

A next step is optional and dependent upon the end application. As shown by step 43, it is possible to select a mandrel 30 in FIG. 3B. If the stent 10 is already in a compact form, it may be possible that no mandrel is required at all. In other applications, the mandrel 30 might become an integral part of the final stent assembly 20. In such an application the mandrel might constitute a balloon portion of a balloon catheter. In still other applications, the mandrel 30 might be used only for manufacture and then removed from the final stent assembly 20. If the stent is to be manufactured as a self-expanding stent, the mandrel 30 might be selected as a tube insert formed of an extruded polymer material as shown in step 44.

Step 45 in FIG.4, is also an optional step in which radiopaque markers 31 and 32 are attached to the mandrel 30, as shown in FIG. 3C. The spacing between the markers 31 and 32 corresponds to the axial length of the stent 10 of FIG. 3A in its compact form.

In step 46 the stent 10, if in an expanded form, is compacted onto the mandrel 30 by applying tension in an axial direction simultaneously with radial compression so the stent will have a low profile that facilitates its introduction into a body passageway. During this process, as shown in FIG.3D, a supplementary mandrel 33 can be positioned in the mandrel 30 for added support. During the compaction process, a filament 34 may be wrapped around the compacted stent 10 and tied to the mandrel 30 in step 47. This filament 34 contains the stent 10 in its compact form for subsequent processing. The filament 34 can comprise any number of materials that contain the stent in its compact form during the processing and do not adhere to the gelatin or other material that impregnates the stent. Elastic filaments containing polymeric silicons are preferred because of advantages in subsequent processing steps; Silastic® filaments are examples.

In step 50, liquid gelatin 35, or a similar liquid, is poured from a container 36 onto the stent 10 while the entire assembly rotates on the mandrel 33. The liquid 35 fills the spaces formed by the interstices of the mesh and the spaces between the filament 34. As the material 35 fills the interstices of the compact stent 10, it cools and begins to form a semi-rigid mass.

In step 51 excess material 35 is wiped from the stent 10 and the material 35 cures to produce an interdisposed restraining structure for maintaining the stent in

its compact form. After the material 35 cures, it is possible to remove the filament 34 from the assembly. If this is an elastic material, then applying tension to the filament 34 reduces its diameter slightly and facilitates its removal from the cured material 35. This leaves the helical groove 22 shown in FIG. 3F that improves the overall flexibility of the stent assembly 20. The stent 10 remains in a compact form because the cured dissolvable material 35, such as cured gelatin, has sufficient strength to contain the stent 10.

If the stent assembly 10 is being manufactured of a self-expanding material, the procedure may then use step 53 to install various end and tip bushings as needed on the mandrel 30, and step 54 to affix a positioning device in the end bushing and to locate the stent assembly in a sheath. During the manufacture of a stent assembly 20 that relies on some external means for expansion, optional step 55 is used to remove the mandrel 30 if that mandrel is not required in the final assembly. If that mandrel is formed of a Silastic material, its removal is facilitated as tensioning the material in an axial direction reduces its diameter and facilitates its removal from a central aperture along the axis of the assembly. In that case the structure that results from the manufacture appears as the structure in FIG. 2 that is adapted for later installation on an expansion or other device. Step 56 represents procedures for finally positioning the stent assembly 20 on a support device.

FIG. 5 discloses an embodiment of a stent delivery system that is adapted for positioning a self-expanding stent assembly in a vessel. As previously indicated with respect to steps 53 and 54, the impregnated stent assembly 20 is mounted on a tubular mandrel 30 with markers 31 and 32. A central aperture 60 through the tubular mandrel 30 enables the tube to slide over a guide wire 61. A tip bushing 62 includes a hollow shank portion 63 and an end portion 64. The shank portion 63 has an outer diameter that interfits with a distal end of a sheath 65 and a center aperture 66 that fits snugly over the tubular mandrel 30. A central aperture 67 in the tip 61 aligns with the central aperture 60 thereby to allow the guide wire 61 to pass through the tip 62.

The proximal end of the sheath 65 terminates at a steering bushing 70 that includes a shank portion 71 that receives the proximal end of the sheath 65 and a head portion 72. The steering bushing 70 has a central aperture or through hole 73 that allows the passage of a pusher tube 74 therethrough. At its proximal end, the pusher tube 74 terminates in a handle or thumb pad 75.

At its distal end, the tube 74 engages an end bushing 80. The end bushing 80 has a proximal shank portion 81 and a distal head portion 82. An aperture 83 is coextensive with at least the head portion 82 and receives the proximal end of the mandrel 30. The shank portion 81 has another aperture 84 that receives the distal end of the pusher tube 74. The diameter of the head portion 82 is selected so it can slide freely within the sheath 65.

In use the guide wire 61 will be located in a body as shown in FIG. 6. Then the assembly, shown in FIG. 5, can be slid over the guide wire 61. During transport the tip bushing 62 seals the end of the stent delivery system and prevents any body fluids 85 from reaching the stent assembly 20 as the stent assembly passes through various vessels 86 in tissue 87. Radiographic or fluoroscopic techniques provide final location information by imaging the markers 31 and 32. The physician can then withdraw the steering bushing 70 toward the pusher tube 74 thereby withdrawing the sheath 65 from the tip bushing 62. This exposes the stent assembly 20 to the body fluids. The fluids, through their temperature and constituents, dissolve the material 21, such as gelatin, over a controlled time interval. As the gelatin dissolves and shifts from a solid phase to a liquid phase, the body fluids flush the gelatin material, now in the liquid phase, from the site, and the stent 10 eventually expands into a final form as shown in FIG. 6. When this occurs, the stent 10 has a much larger diameter than the overall diameter of the stent delivery system including the tip bushing 62, so the entire stent delivery system can be withdrawn along the guide wire 61 and removed from the body.

FIG. 7 depicts an embodiment in which a balloon catheter 91 supports a stent assembly 20 as an example of a stent that requires an external force to expand it. In this particular embodiment a balloon 92 could constitute a mandrel 30 in FIG. 3B to support the stent assembly 20. The remaining portions of the balloon catheter include a central supporting catheter 93 typically with two lumens. A central lumen 94 receives a guide wire 61. A second lumen 95 provides a passage for allowing a balloon control system 96 to inflate and deflate the balloon 92. FIG. 7 also includes the markers 31 and 32 at the opposite ends of the stent assembly 20.

The delivery system in FIG. 7 may or may not be constructed with a protective sheath. If the dissolvable material is selected properly, it is possible to introduce the stent assembly into the body without any protective sheath. In such an embodiment, the body fluids and the temperature will produce slow initial dissolution at the circumferential surface 97 of the stent 10. This surface is relatively smooth and the slight melting produces a lubricating function thereby to allow the structure to transfer through the vessels with minimal trauma.

Once the stent is located in a final position, a sheath, if used, is withdrawn. When the gelatin dissolves, the stent 10 will be freed from the balloon catheter and pumping the balloon catheter expands the balloon 92 thereby forcing the stent 10 into its final position. After this occurs, the balloon control system 96 deflates the balloon 92 and the entire balloon catheter 91 can be withdrawn along the guide wire 61.

In summary, this invention provides an improved stent assembly that uses a cured, dissolvable material to retain a stent in a compact form until it is properly ori-

ented within a vessel. Specific materials for containing the stent are disclosed. Others may also exist or be developed that will shift from a liquid state to a solid state at room temperature and shift back to a liquid state at a controlled rate at temperatures normally encountered in the body. The same material can be utilized with both self-expanding stents and stents that require some external means for expansion.

A stent may be formed in compact form or be compacted from a final form. Different stents can comprise a wide variety of materials or combinations of materials. The stents may be knitted, woven, formed, rolled, extruded or machined. The term "mesh" is exemplary only. Some delivery systems may include external sheaths around the stent assembly; others may not. When a sheath is desirable, the sheath can be very thin because it only needs to provide a smooth exterior surface. There is no requirement for the sheath having sufficient strength to contain a stent. As a result, the overall size of a stent delivery system decreases so it can transfer a stent assembly into smaller vessels. Other configurations of catheters and delivery systems could be substituted for either self-expanding stents or stents requiring some external expansion means.

Although this stent assembly has been described in terms of particular cured dissolvable materials, stent materials and two specific stent delivery systems, it will be apparent that many modifications can be made without departing from the scope of the invention as defined in the appended claims.

Claims

1. A tubular endoprosthesis (20) for inserting in a lumen of a body comprising:

   an expansible wall structure (12) formed of a filament material (11) said wall structure having a first relatively small diameter form for low profile introduction into the lumen, and being expansible in the lumen to form a wall structure having an expanded profile,
   said endoprosthesis being characterised by additionally comprising a cured, solid dissolvable means (21) impregnating said wall structure (12) for containing said wall structure in its first relatively small diameter form, said dissolvable means transforming to a liquid state when said tubular endoprosthesis is in position in the lumen thereby to free said wall structure and enable its expansion in the lumen.

2. A tubular endoprosthesis as recited in claim 1, wherein said expansible wall structure comprises an open fabric of a filament material and has the capability of expanding radially in the body lumen, said cured dissolvable means, in its solid state, retaining said wall structure in its first relatively small diameter form.

3. A tubular endoprosthesis as recited in any of claims 1 and 2, in combination with a delivery system for positioning said tubular endoprosthesis in the body lumen, wherein said delivery system includes a cylindrical sheath (65) for overlying said endoprosthesis, and being retractable from a position overlying said endoprosthesis so as to expose said endoprosthesis and said cured dissolvable means in the body lumen.

4. A tubular endoprosthesis as recited in any of claims 1 through 3, wherein said wall structure is formed by a filament material taken from the group of materials consisting of self-expanding, super-elastic materials, including Nitinol.

5. A tubular endoprosthesis as recited in claim 3, or claim 3 in combination with claim 4, wherein said delivery system additionally includes:

   i. support means (30) for carrying said wall structure,
   ii. distal tip means (62) and proximal bushing means (80) mounted to said support means for preventing axial motion of said wall structure relative to said support means,
   iii. steering means (74) connected to said proximal bushing means for moving said sheath (65) and contained wall structure to a predetermined position in the body lumen, and
   iv. means (70) for moving said sheath relative to said steering means to retract said sheath from said wall structure thereby to enable said cured dissolvable means to dissolve and said wall structure to expand in the body lumen.

6. A tubular endoprosthesis as recited in any of claims 1 through 3, wherein said wall structure is formed by a filament material (11) taken from the group of materials consisting of plastic deformable materials, including stainless steel and tantalum.

7. A tubular endoprosthesis as recited in claim 3, or claim 3 in combination with claim 6, wherein said delivery system additionally includes:

   i. support means (91) for carrying said wall structure,
   ii. distal tip means (62) and proximal bushing means (80) mounted to said support means for preventing axial motion of said wall structure relative to said support means,
   iii. steering means (74) connected to said proximal bushing means for moving said sheath (65) and contained wall structure to a predetermined position in the body lumen,

iv. means (70) for moving said sheath relative to said steering means to retract said sheath from said wall structure thereby to enable said cured dissolvable means to dissolve, and

v. expansion means (92) for expanding said wall structure in the body lumen.

8. A tubular endoprosthesis as recited in any of claims 1 through 7, wherein said cured dissolvable means is formed into discrete axial segments, or is grooved, for improving the flexibility of said tubular endoprosthesis.

9. A tubular endoprosthesis as recited in any of claims 1 through 8, wherein said cured dissolvable means entrains a disparate constituent for release into the body as said cured dissolvable means dissolves.

Patentansprüche

1. Eine rohrförmige Endoprothese (20) zum Einführen in eine Körperöffnung, welche besteht aus:

einer ausdehnbaren Wandstruktur (21), welche aus einem Fasermaterial (11) aufgebaut ist und diese Wandstruktur einen ersten, relativ kleinen Durchmesser besitzt, um kleinvolumig in die Öffnung eingeführt zu werden und welche in der Öffnung ausdehnbar ist, um eine Wandstruktur zu bilden, welche ein ausgedehntes Volumen besitzt,
und diese Endoprothese dadurch gekennzeichnet ist, daß sie zusätzlich ein haltbar gemachtes, stabiles und auflösbares Element (21) beinhaltet, welches die Wandstruktur (12) imprägniert, um die Wandstruktur in seiner ersten Form mit relativ kleinem Durchmesser einzuschließen und das auflösbare Element sich in den flüssigen Zustand verwandelt, wenn die rohrförmige Endoprothese am jeweiligen Ort in der Öffnung sich befindet, um dadurch die Wandstruktur zu befreien und seine Ausdehnung in der Öffnung zu ermöglichen.

2. Eine rohrförmige Endoprothese gemäss Anspruch 1, wobei die ausdehnbare Wandstruktur ein offenes Gewebe aus Fasermaterial beinhaltet und die Fähigkeit besitzt, sich radial in der Körperöffnung auszudehnen und das haltbar gemachte, auflösbare Element in seinem festen Zustand die Wandstruktur in der Form zurückhält, in der sie einen relativ kleinen Durchmesser besitzt.

3. Eine rohrförmige Endoprothese gemäss Anspruch 1 oder 2, in Kombination mit einem Zuführsystem, um die rohrförmige Endoprothese in die Körperöffnung einzuführen, wobei das Zuführsystem eine zylindrische Hülle (65) beinhaltet, um die Endoprothese zu umgeben und welche zurückziehbar aus der die Endoprothese umgebenden Position ist, um die Endoprothese und das haltbar gemachte, auflösbare Element innerhalb der Körperöffnung zu enthüllen.

4. Eine rohrförmige Endoprothese gemäss Anspruch 1 bis 3, wobei die Wandstruktur aus einem Fasermaterial gebildet ist, welches aus der Gruppe von Materialien entnommen ist, welche aus selbstausdehnenden, superelastischen Materialien bestehen, inklusive Nitinol.

5. Eine rohrförmige Endoprothese gemäss Anspruch 1, oder gemäss Anspruch 3 in Kombination mit Anspruch 4, wobei das Zuführsystem zusätzlich beinhaltet:

i. ein Stützelement (30), um die Wandstruktur zu tragen,
ii. eine äußere Spitze (62) und eine mittlere Lagerung (80), welche an dem Stützelement befestigt sind, um eine Axialbewegung der Wandstruktur in Bezug auf das Stützelement zu vermeiden,
iii. eine Steuervorrichtung (74), welche mit der mittleren Lagerung verbunden ist, um die Hülle (65) und die darin beinhaltete Wandstruktur in eine vorgegebene Position in der Körperöffnung zu bewegen, und
iv. ein Element (70), um die Hülle in Bezug auf die Steuervorrichtung zu bewegen, um die Hülle von der Wandstruktur wegzuziehen und um dadurch dem haltbar gemachten, auflösbaren Element zu ermöglichen, sich aufzulösen und um die Wandstruktur in der Körperöffnung auszudehnen.

6. Eine rohrförmige Endoprothese gemäss Anspruch 1 bis 3, wobei diese Wandstruktur aus einem Fasermaterial (11) gebildet ist, welches aus der Gruppe von Materialien entnommen ist, welche kunststoffdeformierbare Materialien beinhaltet, inklusive rostfreier Stahl und Tantal.

7. Eine rohrförmige Endoprothese gemäss Anspruch 1, oder gemäss Anspruch 3 in Kombination mit Anspruch 6 wobei das Zuführsystem zusätzlich beinhaltet:

i. ein Stützelement (91), um die Wandstruktur zu tragen,
ii. eine äußere Spitze (62) und eine mittlere Lagerung (80), welche an dem Stützelement befestigt sind, um eine Axialbewegung der Wandstruktur in Bezug auf das Stützelement zu vermeiden,
iii. eine Steuervorrichtung (74), welche mit der

mittleren Lagerung verbunden ist, um die Hülle (65) und die darin beinhaltete Wandstruktur in eine vorgegebene Position in der Körperöffnung zu bewegen, und

iv. ein Element (70), um die Hülle in Bezug auf die Steuervorrichtung zu bewegen, um die Hülle von der Wandstruktur wegzuziehen und um dadurch dem haltbar gemachten, auflösbaren Element zu ermöglichen, sich aufzulösen und um die Wandstruktur in der Körperöffnung auszudehnen.

v. und eine Ausdehnungsvorrichtung (92), um die Wandstruktur in der Körperöffnung auszudehnen.

8. Eine rohrförmige Endoprothese gemäss Anspruch 1 bis 7, wobei das haltbar gemachte, auflösbare Element aus einzelnen, axialen Segmenten gebildet ist, oder mit Noten versehen ist, um die Flexibilität der rohrförmigen Endoprothese zu verbessern.

9. Eine rohrförmige Endoprothese gemäss Anspruch 1 bis 8, worin das haltbar gemachte, auflösbare Element einen verschiedenartigen Bestandteil zur Freisetzung in den Körper beinhaltet, wenn sich das haltbar gemachte, auflösbare Element auflöst.

Revendications

1. Endoprothèse tubulaire (20) pour être insérée dans un lumen d'un corps comprenant :

   une structure de paroi pouvant se dilater (12) formée d'un matériau de filament (11), ladite structure de paroi ayant une première forme de diamètre relativement petit pour une introduction d'un faible profil dans le lumen, et étant dilatable dans le lumen pour former une structure de paroi ayant un profil dilaté,
   ladite endoprothèse étant caractérisée en ce qu'elle comprend de manière additionnelle des moyens solides cuits pouvant se dissoudre (21) imprégnant ladite structure de paroi (12) pour maintenir ladite structure de paroi dans sa première forme de diamètre relativement petit, lesdits moyens pouvant se dissoudre se transformant en un état liquide lorsque ladite endoprothèse tubulaire est en position dans le lumen libérant ainsi ladite structure de paroi et permettant sa dilatation dans le lumen.

2. Endoprothèse tubulaire selon la revendication 1, dans laquelle ladite structure de paroi pouvant se dilater comprend un tissu ouvert d'un matériau de filament et a la capacité de se dilater radialement dans le lumen du corps, lesdits moyens cuits pouvant se dissoudre, dans leur état solide, retenant ladite structure de paroi dans sa première forme de diamètre relativement petit.

3. Endoprothèse tubulaire selon l'une des revendications 1 et 2, en combinaison avec un système de distribution pour positionner ladite endoprothèse tubulaire dans le lumen du corps, dans laquelle ledit système de distribution comprend une gaine cylindrique (65) pour recouvrir ladite endoprothèse, et pouvant se rétracter à partir d'une position recouvrant ladite endoprothèse de telle manière à exposer dans le lumen du corps ladite endoprothèse et les moyens cuits pouvant se dissoudre.

4. Endoprothèse selon l'une quelconque des revendications 1 à 3, dans laquelle ladite structure de paroi est formée par un matériau de filament choisi dans le groupe de matériaux constitué des matériaux superélastiques autodilatants, comprenant le Nitinol.

5. Endoprothèse tubulaire selon la revendication 3, ou selon la revendication 3 en combinaison avec la revendication 4, dans laquelle ledit système de distribution comprend de manière additionnelle :

   i. des moyens de support (30) pour supporter ladite structure de paroi,
   ii. des moyens de tête distaux (62) et des moyens de douille proximaux (80) montés sur lesdits moyens de support pour empêcher un déplacement axial de la structure de paroi par rapport auxdits moyens de support,
   iii.des moyens de guidage (74) connectés auxdits moyens de douille proximaux pour déplacer ladite gaine (65) et ladite structure de paroi contenue vers une position prédéterminée dans le lumen du corps, et
   iv. des moyens (70) pour déplacer ladite gaine par rapport auxdits moyens de guidage pour rétracter ladite gaine de ladite structure de paroi permettant ainsi auxdits moyens cuits pouvant se dissoudre de se dissoudre et à ladite structure de paroi de se dilater dans le lumen du corps.

6. Endoprothèse tubulaire selon l'une quelconque des revendications 1 à 3, dans laquelle ladite structure de paroi est formée par un matériau de filament (11) choisi dans le groupe de matériaux constitué des matériaux plastiques déformables, comprenant l'acier inoxydable et le tantale.

7. Endoprothèse tubulaire selon la revendication 3, ou selon la revendication 3 en combinaison avec la revendication 6, dans laquelle ledit système de distribution comprend de manière additionnelle :

   i. des moyens de support (91) pour supporter

ladite structure de paroi,

ii. des moyens de tête distaux (62) et des moyens de douille proximaux (80) montés sur lesdits moyens de support pour empêcher un déplacement axial de la structure de paroi par rapport auxdits moyens de support,

iii.des moyens de guidage (74) connectés auxdits moyens de douille proximaux pour déplacer ladite gaine (65) et ladite structure de paroi contenue vers une position prédéterminée dans le lumen du corps,

iv. des moyens (70) pour déplacer ladite gaine par rapport auxdits moyens de guidage pour rétracter ladite gaine de ladite structure de paroi permettant ainsi auxdits moyens cuits pouvant se dissoudre de se dissoudre et à ladite structure de paroi de se dilater dans le lumen du corps, et

v. des moyens de dilatation (92) pour dilater ladite structure de paroi dans le lumen du corps.

8. Endoprothèse tubulaire selon l'une quelconque des revendications 1 à 7, dans laquelle lesdits moyens cuits pouvant de se dissoudre sont formés en segments axiaux discrets ou sont rainurés, pour améliorer la flexibilité de ladite endoprothèse tubulaire.

9. Endoprothèse tubulaire selon l'une quelconque des revendications 1 à 8, dans laquelle lesdits moyens cuits pouvant se dissoudre comportent un constituant séparé pour être libéré dans le corps lorsque lesdits moyens cuits pouvant se dissoudre se dissolvent.

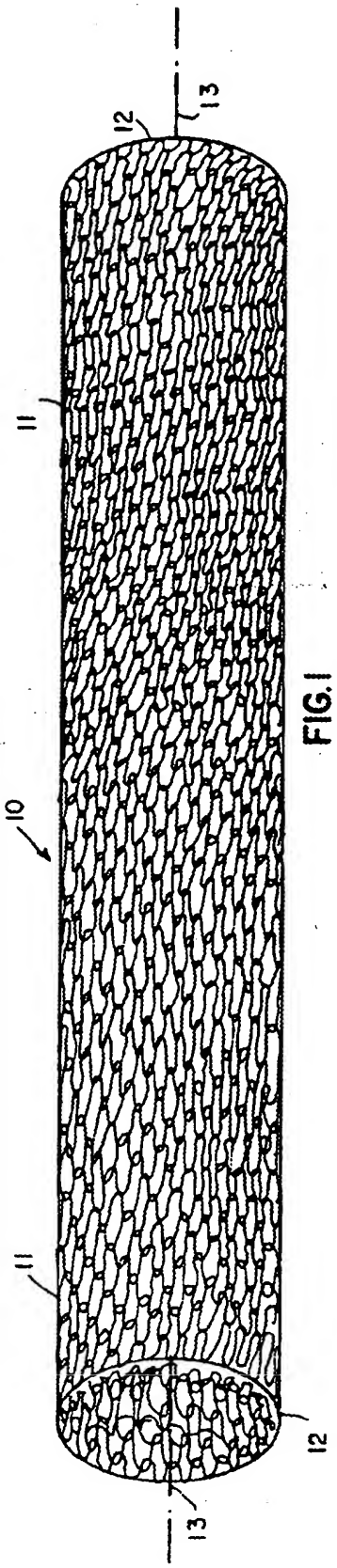


FIG.1

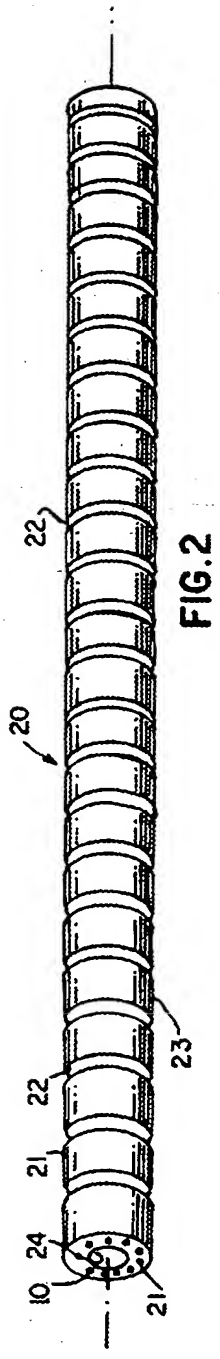


FIG.2

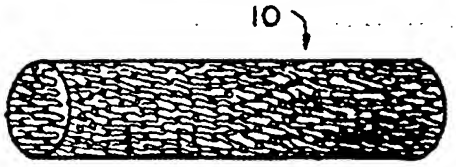


FIG. 3A

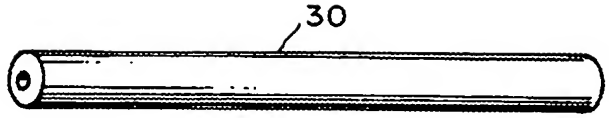


FIG. 3B

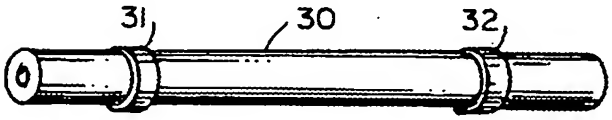


FIG. 3C

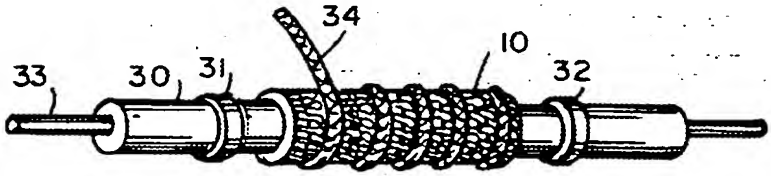


FIG. 3D

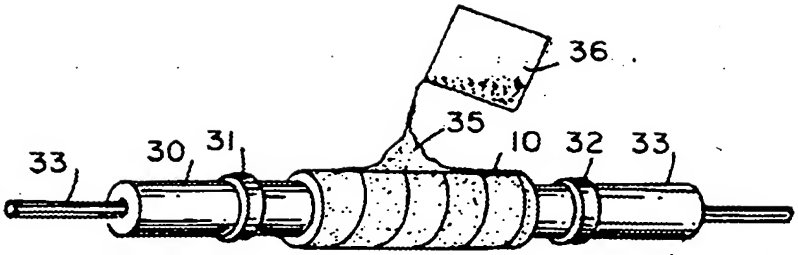


FIG. 3E

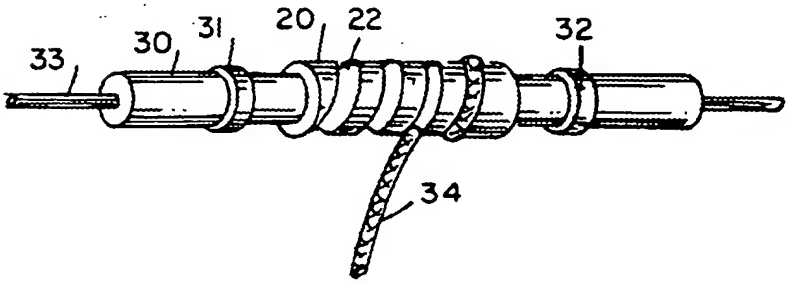
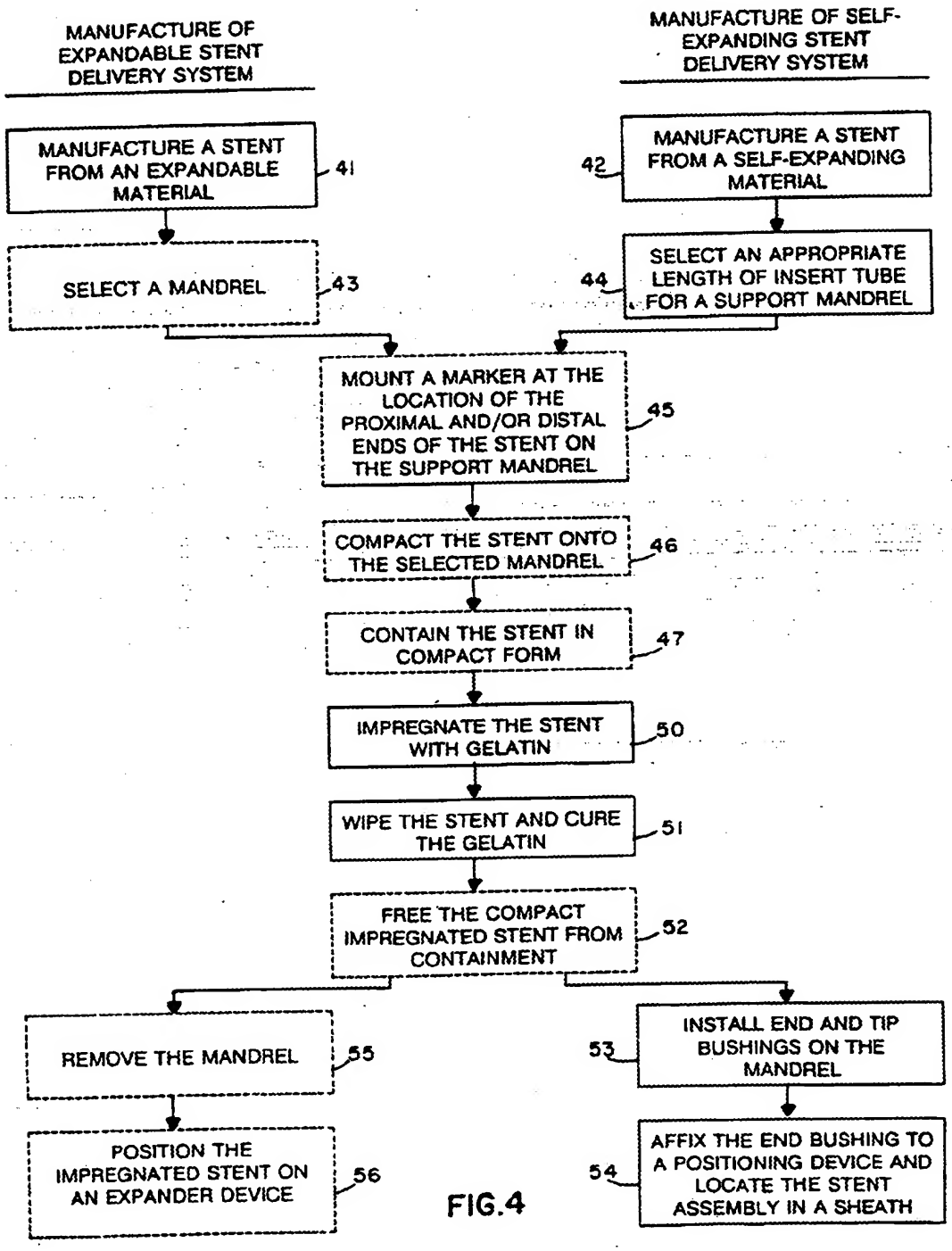


FIG. 3F


MANUFACTURE OF EXPANDABLE STENT DELIVERY SYSTEM
MANUFACTURE OF SELF-EXPANDING STENT DELIVERY SYSTEM
MANUFACTURE A STENT FROM AN EXPANDABLE MATERIAL
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MANUFACTURE A STENT FROM A SELF-EXPANDING MATERIAL
42
SELECT A MANDREL
43
SELECT AN APPROPRIATE LENGTH OF INSERT TUBE FOR A SUPPORT MANDREL
44
MOUNT A MARKER AT THE LOCATION OF THE PROXIMAL AND/OR DISTAL ENDS OF THE STENT ON THE SUPPORT MANDREL
45
COMPACT THE STENT ONTO THE SELECTED MANDREL
46
CONTAIN THE STENT IN COMPACT FORM
47
IMPREGNATE THE STENT WITH GELATIN
50
WIPE THE STENT AND CURE THE GELATIN
51
FREE THE COMPACT IMPREGNATED STENT FROM CONTAINMENT
52
REMOVE THE MANDREL
55
INSTALL END AND TIP BUSHINGS ON THE MANDREL
53
POSITION THE IMPREGNATED STENT ON AN EXPANDER DEVICE
56
AFFIX THE END BUSHING TO A POSITIONING DEVICE AND LOCATE THE STENT ASSEMBLY IN A SHEATH
54

FIG.4

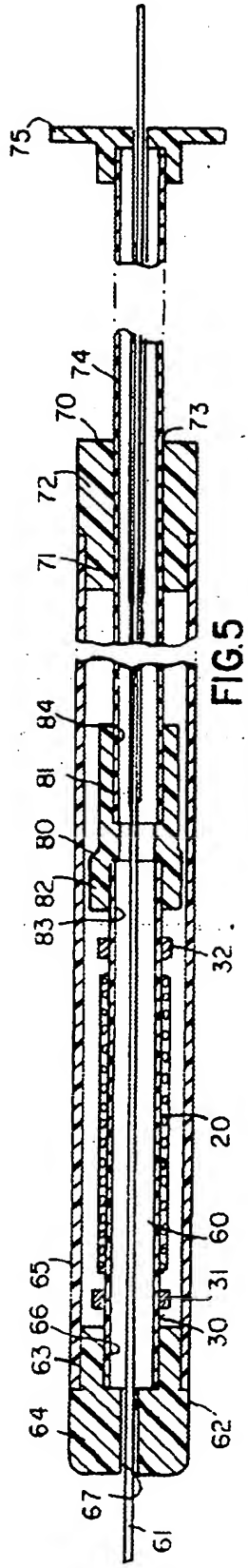
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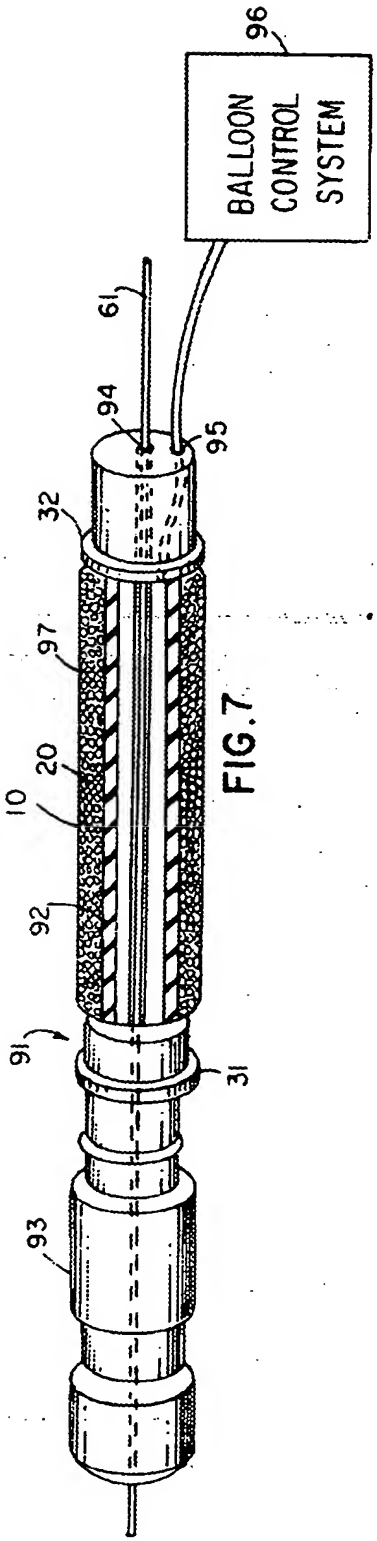
FIG.5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BALLOON CONTROL SYSTEM
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FIG.7

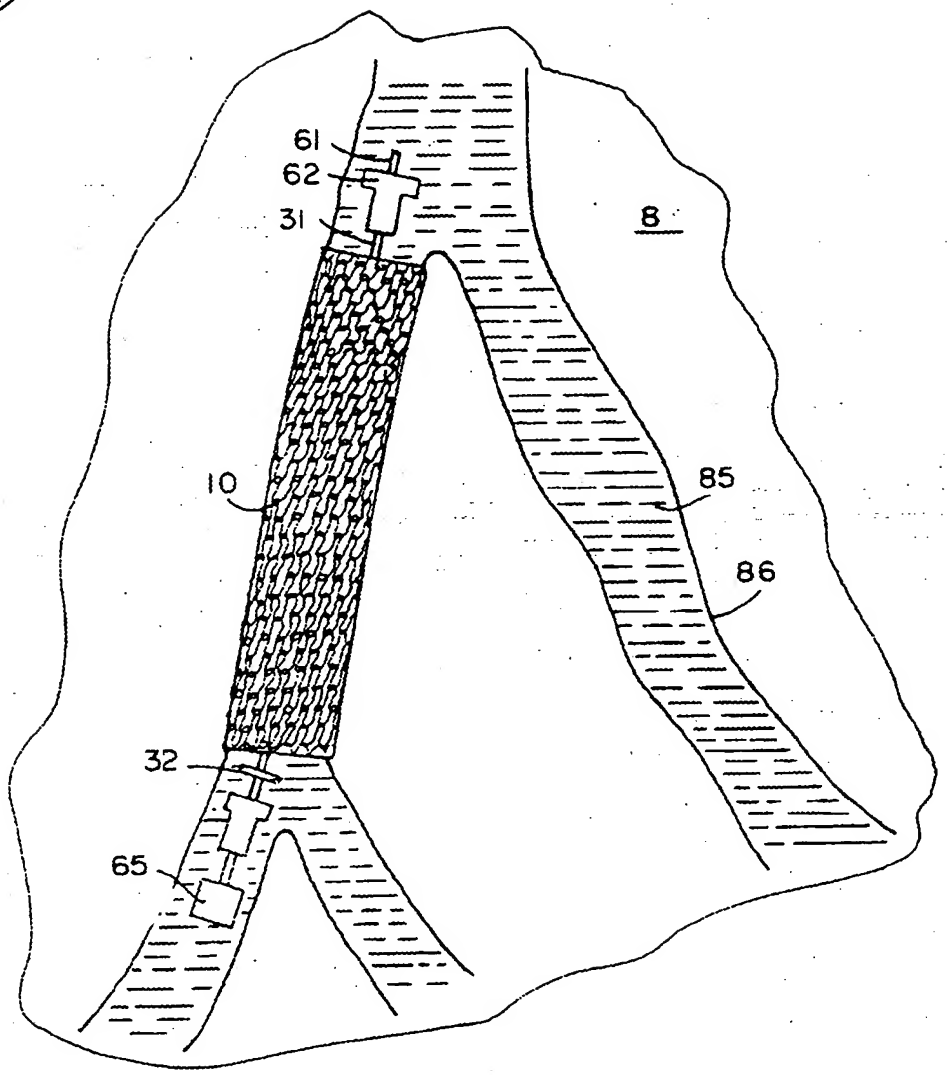

FIG. 6